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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,925	03/09/2001	Christa Hegele-Hartung	SCH-1754-P1	3436

23599 7590 06/17/2002

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	8

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n N .	Applicant(s)	
	09/801,925	HEGELE-HARTUNG ET AL.	
	Examiner	Art Unit	
	Celine Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *7-11,17-22,24,26 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12-16,23,25,27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-29 are pending in the application.

Election/Restrictions

Applicant's election of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 7-11, 17-22, 24, 26 and 28 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-6, 12-16, 23, 25, 27 and 29 are currently under examination.

Claim Objections

Applicant is advised that should claim 1 be found allowable, claim 27 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 12-16, 23, 25, 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention is a method of inhibiting advanced endometrium maturation in a human female or non-human female mammal undergoing fertility treatment by administering a 17α-fluoralkylated progesterone receptor antagonist to said human or mammal. The specification discloses that in a New Zealand White rabbit model, administering a 17α-fluoralkylated progesterone receptor antagonist of formula I following ovarian stimulation with hCG and HMG resulted in delayed endometrium maturation (see example1, page 14).

The state of art at the time of filing does not teach a method of inhibiting advanced endometrium maturation in human or non-human mammal undergoing fertility treatment by administering a progesterone receptor antagonist. Therefore, one skilled in the art would have to rely entirely on the teachings of the specification to use the method as claimed.

The breath of the claims is very broad. The broadest claim encompass a method of inhibiting advanced endometrium maturation in a human or non-human female mammal undergoing fertility treatment by administering a 17α-fluoralkylated progesterone receptor antagonist of formula I at any time and using any dosage.

The teaching of the specification is very limited. The specification only teaches that administering a 17α-fluoralkylated progesterone receptor antagonist to a rabbit following ovarian stimulation with hCG and HMG resulted in inhibition of endometrium maturation. In this experiment, the 17α-fluoralkylated progesterone receptor antagonist (single injection at dosage

0.1, 1, 10 mg/kg) is administered 2 days following hCG injection to induce psuedopregnancy, and 5 days following HMG injection to induce multiple follicular growth (see Figure 1 and Example 1). The specification fails to disclose whether the disclosed dosage is effective in inhibiting advanced endometrium maturation in other mammals or human model. The specification also fails to teach whether administering a 17α-fluoralkylated progesterone receptor antagonist at any time during the fertility treatment can inhibit the occurrence of advanced endometrium maturation. For example, if the compound is administered before hCG or HMG, would it still inhibit the endometrium maturation after hCG and HMG injection? Or if the compound is administered long after post-ovulatory phase, would it reverse the endometrium maturation process? Or would the administration protocol and dosage same for all mammals including human? Therefore, whether administering a 17α-fluoralkylated progesterone receptor antagonist at any time and any dosage during endometrial cycle of a mammal undergoing fertility treatment can inhibit advanced endometrium maturation is unpredictable.

For determining the enablement of the claimed method, the parameters in determining the stage of endometrium maturation is critical. The specification discloses that McPhail-Index, uteroglobin expression and uterine weight are used as parameters to determine the endometrium maturation status. The specification further discloses that rabbits receiving hCG and HMG showed advanced endometrium maturation demonstrated by nearly undetectable uteroglobin expression in endometrial luminal epithelial cells, increased uterine weight and increased McPhail-Index (see page 16, lines 7-11, and table 1). Although the endometrium maturation is inhibited to baseline level (compare to Group 1) by treating rabbits with 0.1mg/kg 17α-fluoralkylated progesterone receptor antagonist, higher concentrations produce confusing results.

At dosage 1 and 10 mg/kg, the McPhail-Index and uterine weight are reduced, however, uteroglobin expression also decreased to untreated level. It is unclear whether at these dosages the endometrium maturation is inhibited. As such, whether administering a 17α-fluoralkylated progesterone receptor antagonist to a mammal undergoing fertility treatment according to the schedule disclosed by the specification is unpredictable. The teachings of the specification are not commensurate in scope with the present claims.

Absent guidance from both prior art and specification, one skilled in the art would have to engage in undue amount of experimentation to practice the method as claimed. Therefore, the specification does not provide the enablement required to use the method as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 12-16, 23, 25, 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 12-16, 23, 25, 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The parameter(s) that determine whether advanced endometrium maturation is inhibited is not recited in the claim. This step is essential to the method as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
June 17, 2002

JAMES KETTER
PRIMARY EXAMINER